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31. (original) In a blood management system according to claim 29 including means for displaying information relating to the location of each of said segments and said patient specimens.

REMARKS

Reconsideration of this application is once again requested in view of the foregoing amendments to the claims and Specification together with submission of an Information Disclosure Statement and references; Affidavit of the inventors as the source of the references (Exhibit A); and marked-up version of claims with Cross-Reference to Specification (Exhibits B and B1) when taken together with the following discussion:

DUTY TO DISCLOSE:

In response to The Duty to Disclose Information Material to Patentability under 37 C.F.R. §1.56, submitted herewith are the publications referred to in applicants' Specification, page 1, under "References to Appended Items" which are the publications applicants deem to be material to patentability. A copy of each of the publications is enclosed, namely:

1. The Table Administration Manual published by Wyndgate Technologies in November, 1999.

2. User's Guide published by Wyndgate Technologies in November, 1999.

3. Reference Manual published by Wyndgate Technologies in November, 1999.

In addition, annexed hereto is an Affidavit of the inventors (Exhibit A) averring that those references are publications of their invention as claimed in the Complete Application and were published on their behalf by the assignee on the dates indicated.

NEW MATTER:

Claims 1 to 26 and 28 to 31 stand rejected under 35 U.S.C. §112, first paragraph. It is the Examiner's position that the claims contain subject matter not described in the Specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed had possession of the claimed invention.

As a preliminary to discussing the rejection of the claims, the term "blood attributes" refers to the antigens on the red blood cells and the antibodies in the serum or plasma as described in the Specification, page 14, line 21 to page 15, line 15 and illustrated in detail in Figures 4A and 4B. The important

factor to the technologist and to this invention is the determination of the presence or absence of these antigens and antibodies, for example, in following the logic used to determine attribute type; i.e., antigen or antibody as well as their presence. Through serologic testing performed by the technologist in the laboratory, a determination is made as to the presence or absence of antigens on the red blood cells and antibodies in the serum or plasma. Once this testing is performed, the technologist enters the results into the computer system, and the system then assigns the presence or absence of the antigens or antibodies based on the results of the testing and corresponding reference tables set up in the system. Again, this is in complete contradistinction to Cox et al which electronically compares only the ABO attributes. Stated another way, Cox et al compares only ABO/Rh compatibility but does not actually perform a physical compatibility test between the blood products and patient specimens for other antigens and antibodies. Thus, in order to define the metes and bounds of the term as applied to applicants' invention, the claims have been amended to recite "determining the antigens and antibodies present in said one of said blood products and said patient specimens" and in a subsequent step "determining the compatibility of said one of said blood products and patient specimen selected by comparing the antigens and antibodies . . . ." It should be noted that the terms "antigen" and "antibody" are defined on page 3 of the Specification.

Claims 1, 2-20, 29-31 and claims dependent therefrom are rejected under 35 U.S.C. §112, first paragraph, for failure to provide support, page and line number for all amended and newly-added claims. In the previous amendment entered July 28, 2003, the REMARKS dealing with the claims in issue contained reference by page and line number to support in the Specification for all amended and newly-added claims. See for example pages 12 to 15 of the REMARKS. The Examiner made no acknowledgement of this in his repeated rejection based on lack of support and it is therefore not clear whether the Examiner was merely repeating his rejection or referring only to specific language in the claims, such as, "all of said blood attributes" as well as the term "blood attributes" which in his opinion still were not supported by the Specification.

In addition, in order to supplement the previous references made to the Specification, annexed hereto as Exhibit B is a Marked-Up Version of the Claims from the amendment entered July 28, 2003 with appropriate Cross-Reference to Specification for each of the amendments and newly-added claim 31 appearing therein. It is therefore submitted that support can be found for each of the elements and steps recited in the claims as previously amended with the possible exception of "blood attributes" which refers to the antigens on the red blood cells and the antibodies in the serum or plasma as described in the Specification, page 14, line 21 to page 15, line 15 and illustrated in detail in Figures 4A and 4B. In addition, clear support can be found in Exhibit B1 for the amended claims presented in this amendment.

VAGUE AND INDEFINITE

Claims 1, 11, 12, 13, 15, 20, 30 and the claims dependent therefrom have been rejected for the reason that the phrases "all blood attributes"/"blood attributes"/"all attributes"/"said attributes" are considered to be vague and indefinite. These phrases have been amended to recite "antigens and antibodies" as discussed at greater length earlier in the REMARKS.

Claim 21 has been amended to omit reference to "fifth" and is intended neither to replace "fifth means" nor be a part of the "fifth means" of claim 20.

LACK OF ANTECEDENT BASIS

Claim 12 has been amended to be dependent from claim 11 and therefore has proper antecedent basis for the phrase "said antigens and antibodies".

OBJECTION TO DISCLOSURE

The language "Reference is made to the microfiche appendix attached hereto and incorporated herein as a part thereof" has been deleted on page 1 of the Specification. Applicants' attorney has obtained a paper copy of the microfiche appendix from the Provisional Application.

It is urged that the claims as now presented for consideration are in allowable condition and action to that end is courteously solicited. If any issues remain to be resolved, it is requested that the Examiner contact attorney for applicant at the telephone number listed below.

Respectfully submitted,

By: John E. Reilly
Registration No. 18,476
Attorney for Applicants
1554 Emerson Street
Denver, Colorado 8018
Area Code 303 839-8700

CERTIFICATE UNDER 37 C.F.R. 1.8

I hereby certify that the foregoing Amendment is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231, this 20th day of February, 2004.

Mary J. Robertson

EXHIBIT A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Patent Application of	:	Dated:
Csore, M. et al	:	
Serial No.: 09/823,814	:	Group: Art Unit 1631
Filed: 30 March, 2001	:	
For: METHOD AND SYSTEM FOR MANAGING BLOOD PRODUCTS	:	Examiner: Mahatan, C.
	:	Action: AFFIDAVIT UNDER 37 C.F.R. §1.132

MAIL STOP: NON-FEE AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

We, Miklos Csore, Gerald F. Willman, Jr. and Noah L. Bentley of 642 Jones Way, Sacramento, California 95818, 572 Owl Creek Drive, Powder Springs, Georgia 30127 and 1876 Ardfern Way, Folsom, California 95630, respectively, being duly sworn, depose and say:

1. That we are the inventors of the above-identified application for patent Serial No. 09/823,814, filed March 30, 2001 and which claims the benefit of Provisional Application Serial No. 60/193,819, filed 31 March, 2000 for METHOD AND SYSTEM FOR MANAGING BLOOD PRODUCTS.

2. That said above-identified Provisional Application and Complete Application were assigned to Global Med Technologies, Inc. d/b/a Wyndgate Technologies, and said Provisional Application and Complete

Application incorporate by reference the following publications:

A. The Table Administration Manual published by Wyndgate Technologies in November, 1999.

B. User's Guide published by Wyndgate Technologies in November, 1999.

C. Reference Manual published by Wyndgate Technologies in November, 1999.

3. That said references are publications of our invention claimed in said Complete Application and were published on our behalf by said assignee, Global Med Technologies, Inc. d/b/a Wyndgate Technologies on the dates referred to above.

Further affiants sayeth not.

Miklos Csore

STATE OF California)
) ss.
COUNTY OF El Dorado)

Before me, a Notary Public in and for the said County and State, personally appeared Miklos Csore, known to me to be the person whose name is subscribed to the foregoing instrument, and acknowledged to me that he executed the same for the purposes and consideration therein expressed.

Given under my hand and seal of office this 30th day of January, 2004. My commission expires 05/5/07.

MELBA HENDERSON
COMM. #1411806
Notary Public-California
EL DORADO COUNTY
My Comm. Exp. May 15, 2007

Melba Henderson
Notary Public

Gerald F. Willman, Jr.

STATE OF Georgia)
) ss.
COUNTY OF cobb)

Before me, a Notary Public in and for the said County and State, personally appeared Gerald F. Willman, Jr., known to me to be the person whose name is subscribed to the foregoing instrument, and acknowledged to me that he executed the same for the purposes and consideration therein expressed.

Given under my hand and seal of office this 2nd day of February, 2004. My commission expires Notary Public, Cobb County, Georgia My Commission Expires Jan. 28, 2007.

Notary Public

Noah L. Bentley

STATE OF California)
) ss.
COUNTY OF El Dorado)

Before me, a Notary Public in and for the said County and State, personally appeared Noah L. Bentley, known to me to be the person whose name is subscribed to the foregoing instrument, and acknowledged to me that he executed the same for the purposes and consideration therein expressed.

Given under my hand and seal of office this 30th day of January, 2004. My commission expires 051507.

MELBA HENDERSON
COMM. #1411806
Notary Public-California
EL DORADO COUNTY
My Comm. Exp. May 15, 2007

Melba Henderson
Notary Public

20 February, 2004

Serial No.: 09/823,814 : Group: Art Unit 1631
Filed: 30 March, 2001 :
For: METHOD AND SYSTEM FOR : Examiner: Mahatan, C.
MANAGING BLOOD PRODUCTS :

EXHIBIT B

SUPPORT IN SPECIFICATION FOR AMENDMENTS TO CLAIMS FROM AMENDMENT DATED DECEMBER 27, 2002:

Here, bracketing indicates deleted matter and underlining is employed for matter added 12/27/02, or as further amended by the present amendments to the Claims.

1. A [programmable] method of managing and tracking blood products between a plurality of remote patient facilities and a central blood testing facility <u>wherein a blood specimen is obtained from each patient who requires a blood reserve for possible transfusion and said specimen is transferred to said central blood testing facility</u> comprising the steps of:

Cross Reference to Specification:

Page 12, lines 11-16
Figures 2 and 3

[obtaining a blood specimen from each patient who requires a blood reserve;] providing an inventory of blood products at said central blood testing facility;

Cross Reference to Specification:

Page 5, line 21 to page 6, line 1
Page 6, line 12 to page 7, line 1
Page 12, lines 22 to 26
Figures 2 and 3

selecting [a] one of said blood [product for crossmatching with each said patient specimen] products which has an available segment at said central blood testing facility;

Cross Reference to Specification:

Page 2, lines 17-18
Page 13, lines 21-24
Figures 2 and 3

detaching said segment from said blood product at said central blood testing facility;

Cross Reference to Specification:
Page 6, lines 6-10 and lines 17-20
Page 13, lines 12-14
Figures 2 and 3

JER: see page 4, line 11 for "detach" no other detach or detaching"

transferring said blood products from said central blood testing facility to one of said remote patient facilities at which said patient is located;

Cross Reference to Specification:

Page 6, line 12 to page 7, line 1
Page 12, lines 17-26
Figures 2 and 3

assigning said segment to said patient specimen for crossmatching at said central blood testing facility;

Cross Reference to Specification:

Page 6, line 12 to page 7, line 1
Page 13, lines 17-27
Figure 3

remote serological crossmatching each said patient specimen and said segment of said blood product at said central blood testing facility to determine their compatibility with one another; [and]

Cross Reference to Specification:

Page 11, line 1 to page 14, line 21
Figures 2 and 3

determining all of the blood attributes of said one of said blood products and said patient specimen;

Cross Reference to Specification:

Page 3, lines 17 to 24

Page 7, lines 2-8
Figures 5, 6

determining the compatibility of each said blood products and patient specimen selected by comparing all of said blood attributes thereof;

Cross Reference to Specification:

Page 6, line 2 to page 7, line 1
Page 14, line 22 to page 16, line 16
Figures 3, 4a, and 4b

managing said blood products by preparing a patient identification database of each of said blood products , segments and patient specimens [determined to be compatible] and storing information in said database at each of said central blood testing and remote patient facilities [correlating] which correlates each of said blood products , segments and patient specimens , their location and movement; and

tracking the location and movement of each of said blood products, segments and patient specimens in said database between said remote patient facilities and said central blood testing facility by displaying the information stored in said database relating to their location and movement.

Cross Reference to Specification:

Page 6, line 12 to page 8, line 21
Page 12, line 1 to page 14, line 21
Page 24, line 14 to page 25, line 11

Figures 1, 2, 3, 18, 19, 22

3. The method according to claim 1 including the step of assigning said blood products and said patient specimens to a location within each of said remote patient facilities and said central blood testing facility and tracking any movement of said blood products and said patient specimens to other locations.

Cross Reference to Specification:

Page 6, line 12 to page 7, line 1
Page 12, line 11 to page 14, line 21
Figures 1-3, 22

4. The method according to claim 1 including the step of [determining types of blood attributes of each of said blood products and said patient specimens] displaying said patient identification information on a computer at each of said remote patient facilities and central blood testing facility.

Cross Reference to Specification:

Page 7, lines 9-15
Figures 8-17, 20-21

5. The method according to claim [1] 4 including the step of [determining compatibility of said blood product and said patient specimen by comparing the types of blood attributes thereof] displaying said information on a patient bar on each said computer which is accessible to all users regardless of their location at each of said facilities.

Cross Reference to Specification:

Page 17, line 20 to page 24, line 13
Figures 8-17, 20-21

6. The method according to claim 1 further characterized by crossmatching a segment of each said blood product and each said patient specimen at said central blood testing facility, assigning each said segment and each said patient specimen to a location in said central blood testing and remote patient facility, and recording said location in said database.

Cross Reference to Specification:

Page 6, line 12 to page 7, line 1
Page 12, line 11 to page 14, line 21
Figures 18 and 19

7. The method according to claim [1] 2 including the step of selectively displaying the absence or presence of each item of information stored including special needs, patient comments, prior transfusion reaction history, autologous blood availability, directed blood components, blood type , presence of unexpected antibodies, [and] patient specimen expiration date and reserved blood components.

Cross Reference to Specification:

Special Needs, patient comments:

Page 18, line 5 to page 19, line 8
Figures 8-10

Presence of unexpected antibodies:

Page 21, line 20 to page 22, line 16
Figures 8, 14

Reserved blood components:
Page 23, lines 18 to page 24, line 4
Figures 8, 17

8. The method according to claim 1 wherein the step of cross-matching includes the step of producing a product identification tag and attaching to each said blood component [found to be compatible].

9. The method according to claim [9] 1 [including] wherein the step of determining the blood attributes is characterized by comparing the antigens and antibodies in each of said blood products and said patient specimens to determine whether each is present in each segment of said blood product and said patient specimen tested and storing said information in said database.

Cross Reference to Specification:

Page 14, line 22 to page 16, line 12
Figures 4a, 4b, 5, 6, 18, 19

10. [In a programmable blood management system] A method for managing and tracking blood products , patient specimens and segments between a plurality of hospitals and a central blood [test] testing facility wherein a computer database is provided for recording information and a screen is provided for displaying said information, the method comprising the steps of:

Cross Reference to Specification:

Page 11, line 9 to page 14, line 21
Figures 1-3

obtaining a blood specimen from each patient requiring a blood [reserve] product to be reserved for possible transfusion;

Cross Reference to Specification:

Page 2, lines 1-18
Page 12, lines 16-17

assigning a segment of a blood product for crossmatching;

remote serological crossmatching each said segment and said patient specimen at said facility to determine their compatibility with one another;

Cross Reference to Specification:

Page 12, line 11 to page 14, line 21

managing each said segment and said patient specimen crossmatched by identifying each said segment, said component and said patient specimen [determined to be compatible] with patient identification information and recording said patient identification information on said database; and

Cross Reference to Specification:

Page 13, line 12 to page 14, line 14
Figures 18 and 19

[recording said patient identification information on said database]

tracking the location and movement of each of said segments, said products and said patient specimens between said hospitals and said facility.

Cross Reference to Specification:

Page 6, line 2 to page 7, line 1
Page 24, line 14 to page 25, line 20
Figures 1-3

11. [In a system] A method according to claim 10 further characterized by determining [blood type] attributes of each of said blood products and said patient specimens prior to said crossmatching.

12. [In a system] A method according to claim 10 including the step of testing the compatibility of said [blood type] attributes prior to said crossmatching.

13. [In a system] A method according to claim 12 characterized by periodically updating said [blood type] attributes and recording said information in said database.

14. [In a system] A method according to claim 10 including the step of tracking the location of each said segment

and said patient specimen by recording [its] their movement between said test facility and patient location.

15. [In a system] A method according to claim 10 including the step of recording blood attributes of each said patient specimen in said database.

16. [In a system] A method according to claim 10 including the step of recording prior transfusion reaction history of each said patient in said database.

17. [In a system] A method according to claim 10 including the step of recording autologous blood availability in said database.

18. [In a system] A method according to claim 10 including the step of recording blood type of each said blood product and said patient specimen.

19. [In a system] A method according to claim 10 including the step of recording the specimen expiration date of each said segment and said patient specimen.

20. A system for managing blood products and tracking their movement between a central blood test facility and a plurality of hospitals wherein a computer is provided for processing data including a screen for displaying information, said system comprising:

managing means having first means including a database for entering information pertaining to each patient requiring a blood reserve [;] , second means for entering blood type information for a blood specimen from each said patient [;] , third means for recording a blood type for a blood product assigned to each said patient , fourth means for recording on said database results of comparing blood attributes of each said patient specimen and said blood product;

Cross Reference to Specification:

Page 14, line 22 to page 15, line 30
Figures 4a, 4b, 5, 6, 18 and 19

[and]

[fourth] fifth means for recording on said database results of serological crossmatching of each said patient specimen and said blood product; and

tracking means for tracking the location and movement of each of said blood products and patient specimens between said blood test facility and said hospitals by displaying on said screen the information stored in said database relating to their location and movement.

Cross Reference to Specification:

Page 6, line 2 to page 7, line 1
Page 24, line 14 to page 25, line 20
Figures 1-3

29. [A] In a [programmable] blood management system for managing [and tracking] information relating to blood products [for use] between a central blood test facility and one or more remote patient facilities wherein a computer is provided for processing data, a database is provided for recording said information and a screen is provided for displaying said information recorded, the improvement comprising:

managing means including means for recording information identifying each patient requiring a blood reserve on said database [;] , means for obtaining and recording a blood specimen from each said patient[;] , means for assigning a segment of a blood product for crossmatching [;] , means for remote serological crossmatching each said segment and said patient specimen at said blood test facility to determine their compatibility with one another [;] , means for identifying each said segment and said patient specimen [determined to be compatible;] , and means for assigning said segment , said blood product and said patient specimen to a location in one of said blood test facility and said remote patient facilities.

Cross Reference to Specification:

Page 5, line 21 to page 7, line 1
Page 7, line 17 to page 8, line 12

31. In a [programmable] blood management system according to claim 29 including means for displaying information relating to the location of each of said segments and said patient specimens.

Cross Reference to Specification:

Page 5, line 21 to page 7, line 1
Page 24, line 14 to page 25, line 20
Figures 1-3

20 February, 2004

Serial No.: 09/823,814	:	Group: Art Unit 1631
Filed: 30 March, 2001	:	
For: METHOD AND SYSTEM FOR MANAGING BLOOD PRODUCTS	:	Examiner: Mahatan, C.

EXHIBIT B1

SUPPORT IN SPECIFICATION FOR AMENDMENTS TO CLAIMS FROM CONCURRENT AMENDMENT:

1. (currently amended) A method of managing and tracking blood products between a plurality of remote patient facilities and a central blood testing facility wherein a blood specimen is obtained from each patient who requires a blood reserve for possible transfusion and said specimen is transferred to said central blood testing facility comprising the steps of:

providing an inventory of blood products at said central blood testing facility;

selecting one of said blood products which has an available segment at said central blood testing facility;

detaching said segment from said blood product at said central blood testing facility;

transferring <u>said</u> one of said blood products from said central blood testing facility to one of said remote patient facilities at which said patient is located;

assigning said segment to said patient specimen for cross-matching at said central blood testing facility;

<u>determining the antigens and antibodies present in said one of said blood products and said patient specimens</u>;

Cross Reference to Specification:

Page 4, line 21 to page 15, line 15
Figures 4A and 4B

remote serological cross-matching each said patient specimen and said segment of said blood product at said central blood testing facility to determine their compatibility with one another;

~~determining all of the blood attributes of said one of said blood products and said patient specimen;~~

determining the compatibility of said one of said blood products and patient specimen selected by comparing ~~all of said blood attributes thereof~~ the antigens and antibodies in said one of said blood products and said patient specimens to determine whether each is present in each segment of said blood product and said patient specimen tested, and storing said information in said database thereof;

Cross Reference to Specification:

Page 6, line 2 to page 7, line 1
Page 14, line 22 to page 16, line 16
Figures 3, 4a, and 4b

managing said blood products by preparing a patient identification database of each of said blood products, segments and patient specimens and storing information in said database at each of said central blood testing and remote patient facilities which correlates each of said blood products, segments and patient specimens, their location and movement; and

tracking the location and movement of each of said blood products, segments and patient specimens in said database between said remote patient facilities and said central blood testing facility by displaying the information stored in said database

relating to their location and movement.

11. (currently amended) A method according to claim 10 further characterized by determining ~~all~~ the blood attributes of each of said blood products and said patient specimens by the presence of antigens and antibodies in each said segment and said patient specimen tested prior to said cross-matching.

Cross Reference to Specification

Page 3, lines 17 to 24
Page 7, lines 2-8
Figures 5, 6

13. (currently amended) A method according to claim 12 characterized by periodically updating ~~said attributes~~ the compatibility of said antigens and antibodies and recording said information in said database.

Cross Reference to Specification

Page 16, lines 2 to 9
Page 25, line 6